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PATENT APPLICATION

Our Docket No. 910022.ORI

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re App	:	Michael R. Forman	June 24, 1993
S.N.	:	07/800,201	Art Unit 3306
Filed	:	November 29, 1991	Examiner Anthony Gutowski
For	:	LASER BONDING OF ANGIOPLASTY BALLOON CATHETERS	

DECLARATION OF MICHAEL R. FORMAN

Michael R. Forman hereby declares as follows:

1. That he is employed by Schneider (USA) Inc., the assignee of this application, as Senior Development Engineer, and that he has been an employee of Schneider since about July, 1990. During this period, he has devoted approximately one-half of this time to investigating the formation of bonds between materials used in catheters and dilatation balloons.

2. From 1988 to 1990 he worked for a division of Johnson & Johnson, designing optical systems for blood analyzers.

3. From 1984 through 1988 he was an employee of Minnesota Laser Corporation where he designed mechanical and optical components for surgical laser systems.

4. He earned his Bachelor of Arts degree in Philosophy at the University of California at Santa Cruz, while also taking extensive coursework in Physics. Presently, while a full-time employee of Schneider, he is taking graduate courses toward a degree of Master of Science in Manufacturing Systems. In this graduate program, he has completed coursework in polymers, including their fusion bonding properties.

5. He is the inventor named in the above-identified application for U.S. patent. He is familiar with an Office Action dated September 24, 1992 (September 92 Action) in this

application, and an Office Action dated March 31, 1993 (March 93 Action) in this application and is familiar with certain prior art cited in these Office Actions: namely, U.S. Patent No. 4,958,634 (Jang); U.S. Patent No. 4,950,239 (Gahara et al); and U.S. Patent No. 4,276,874 (Wolvek et al).

6. He is aware that all of these cited patents disclose heat boding, heat welding or heat sealing of the polymers that form catheters and dilatation balloons. He is aware that only the Jang patent mentions laser bonding.

7. He is aware that the Jang patent also mentions vulcanization bonding, solvent bonding and ultrasonic bonding. Those of skill in the art do not employ vulcanization bonding, solvent bonding, or ultrasonic bonding. In fact, ultrasonic bonding is typically used on flat plates which is entirely inconsistent with the physical constraints of annular or semi-circular bonds of balloon necks and catheter tubing.

8. The term "heat bonding" is understood by those of skill in the art as a contact method, for example, pressing the balloon necks against the catheter with copper jaws. This method relies principally upon conduction of heat radially inward through the necks and into the catheter, to insure sufficient heat for fusion at the bond site. The inevitable result is crystallization and stiffening of the balloon and catheter material, not only at the bond site, but also in both axial directions away from the bond. Heat radiated by the jaws also contributes to crystallization.

9. Conventional "non-contact" fusion bonding methods, such as the heat sealing method disclosed in U.S. Patent No. 4,252,305 (Becker et al), also rely primarily upon heat conduction and result in crystallization well beyond the bond site.

10. Even fusion bonding by laser -- if performed without appropriate matching of the laser wavelength and the polymeric materials of the catheter and dilation balloon -- is subject to

substantial crystallization beyond the intended fusion bond area. When the laser wave length employed is not matched to the highabsorptive band widths of the polymers, the polymers tend to conduct heat away from the bond site, rather than absorb the laser energy at the bond site. The result is substantial crystallization in areas beyond the bond site.

11. Accordingly, the mere use of laser energy to produce the fusion bond does not inherently result in a catheter in which tapered regions of the dilatation balloon are within .030 inches of the fusion bond, yet are substantially free of crystallization.

12. With particular reference to the March '93 Action, he addresses certain contentions in that Action as follows:

(a) As to several occurrences of the phrase "conventional laser bonding" on page 2 of the March '93 Action:

There is no such thing as "conventional laser" bonding. To his knowledge, no one other than Schneider markets or has been able to market a balloon catheter manufactured by laser bonding. The "conventional" form of bonding is heat bonding as discussed above. The Jang patent does nothing more than list laser welding as one of several alternative approaches to forming the bond.

(b) As to the contention on page 2 that fusion bonds on the neck regions would inherently be immediately adjacent the balloon tapered regions "to prevent inflation of the neck regions upon balloon inflation":

The assumption - that but for the fusion bond, the neck region would inflate along with the

balloon - is incorrect. The reason the neck regions do not inflate is the greater thickness of the wall at the neck region, as compared to the balloon wall thickness, and to a lesser extent the reduced diameter at the neck region. For example, a neck region wall thickness of .0015 inches - .0020 inches typically is associated with a balloon wall thickness of .0004 inches. Hoop strength is determined according to the equation:

$$\sigma = \frac{pd}{2t}$$

where sigma is the stress, p is the pressure, d is the diameter and t is the thickness. Thus, there is no requirement for a fusion bond immediately adjacent the balloon tapered region to prevent neck region inflation. Wall thickness and reduced diameter prevent such inflation.

(c) As to the contention on page 2 that balloon tapered regions of the Jang catheter would inherently be substantially free of crystallization to allow proper balloon inflation and deflation:

Under conventional fusion bonding methods, the tapered regions are free of crystallization <u>only</u> if the bond is sufficiently spaced apart axially from the tapered region (i.e. by a distance well over .030 inches). Only under the bonding method as taught in the present application is the balloon tapered region substantially free of crystallization, despite the fusion bond being within .030 inches of the tapered region. Certain balloon catheters sold by

Schneider (USA) Inc., being the only balloon catheters manufactured according to the method disclosed in the present application, are the only balloon catheters exhibiting the substantial freedom from crystallization despite fusion bonds closely adjacent the tapered regions.

(d) As to the contention at page 4 that rapid cooling eliminates crystallization:

While more rapid cooling reduces crystallization, crystallization always is present. This is why fusion bond areas are opaque, while areas away from the bond are more transparent. Cooling jackets and other rapid cooling means have been used in attempts to reduce crystallization, but without success.

(e) as to the contention on page 5 that crystallization requires a polymer to be heated above the melting temperature and therefore converted from a solid phase to a liquid phase:

This assumption is incorrect. PET and other crystallizable polymers have a glass transition temperature (T_g), below the melting point. When a crystallizable polymer is heated above the glass transition temperature, although kept at a temperature below the melting point, it assumes a rubbery consistency. There is no transition from the solid phase to the liquid phase. Yet, crystallization occurs. Thus, crystallization does not require heating above the melting point, nor does it require a transition from the solid phase to the liquid phase.

(f) As to the contention on page 5 that in

conventional heat fusion only the neck region is raised to the melting point, since reaching the melting point in other regions, (i.e. the balloon tapered portion) would cause melting and loss of structural integrity and shape:

This contention, even if assumed correct, does not support an assumption that crystallization is avoided merely by keeping the temperature below the melting point. See the response to contention (e) immediately above.

13. As compared to the Jang patent, the Gahara and Wolvek patents are even more remote from the present invention, because they disclose only conventional heat bonding, heat welding or heat sealing to form fusion bonds. These bonding methods would not inherently result in dilatation balloon tapered areas substantially free of crystallization. In fact, given the close proximity of the fusion bond, substantial crystallization in the tapered portions would be an inherent result.

14. As taught in the present application, the laser energy source, and the polymers forming the dilatation balloon and the catheter, are selected with care to match the laser energy wave length with a high absorption bandwidth of the polymeric material. The laser energy is carefully focused at the bond site, i.e. the interface of the balloon neck and catheter tubing. Finally, the laser is operated in the tem_{00} mode, providing a Gaussian distribution that further tends to concentrate the laser energy at the bond site.

15. Because of the effective concentration, less energy is required to form the fusion bond. The tendency of the polymeric material to absorb rather than conduct the energy further reduces the energy required for fusion. With less energy required, and more of the energy remaining at the bond site, there is no

substantial crystallization beyond about 0.10 inches from the bond site. This result is not achieved under conventional fusion bonding. This result is not achieved using laser bonding, unless the laser wavelength and polymers are appropriately matched.

16. He hereby declares that all statements herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful and false statements may jeopardize the validity of this application or any patent issued thereon.

Date: June 25, 1993

Michael R. Forman

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